RESEARCH PLAN OF THE PUERTO RICAN CENTER ON HEALTH DISPARTITIES

Introduction and Overview of the Entire CPHHD Application

A. Specific Aims

The National Institutes of Health (NIH) has announced its commitment to eliminating health disparities among older adults through the **NIH Strategic Plan to Reduce and Ultimately Eliminate Health Disparities.** The NIH has proposed a mission to improve the nation's health by uncovering new knowledge in the prevention, detection, diagnosis, and treatment of disease and disability, with the ultimate goal of reducing and eliminating health disparities among racial and ethnic minorities(Kubzansky, Kawachi et al. 1999; NIMH 2002). Although health disparities are well documented among minority populations, they have not been fully explained by socio-economic status(Adler, Boyce et al. 1993; Adler, T. Boyce et al. 1994.). Hispanics have been shown to be at particular risk for several chronic conditions(Council on Scientific Affairs 1991; Crisostomo 2002; NIMH 2002). In a previous study funded by the National Institute on Aging (NIA) we have demonstrated that Puerto Rican elders in Massachusetts are significantly more likely to have physical disability, depression, cognitive impairment, diabetes and other chronic health conditions than do non-Hispanic white elders **living in the same neighborhoods**(Falcon and Tucker 2000; Tucker, Bermudez et al. 2000; Tucker, Falcon et al. 2000; Bermudez and Tucker 2001; Tucker KL 2001; Chen H 2002; Castaneda, Bermudez et al. in press; Lin H In press). This suggests that the disparity is not due to physical or neighborhood location, but rather that other factors must be influencing these differences. In that study, we also showed that the Puerto Rican elders had diets that were limited in diversity and were relatively low in micronutrient content(Martin, Bermudez et al. 2000; Tucker, Borwankar et al. 2000; Falcon and Tucker 2001; Bermúdez, Ribaya-Mercado et al. 2002; Kwan L 2002). In the proposed Center for Puerto Rican Nutrition and Health, we will investigate the relationships between psychosocial stress, as experienced by the older adult Puerto Rican population in Boston, MA, and its effect on physiologic burden or "allostatic load"; and in turn how this is associated with functional outcomes that we previously identified as areas of health disparity: depression, cognitive impairment and functional limitation. We further propose that the association between life stress, physiologic response and chronic conditions is modified by nutritional status, with a focus on B and antioxidant vitamins, and by social support.

The overall aim of this Center is to perform a series of inter-related studies involving a cohort of older adults of Puerto Rican origin to evaluate specific stressors affecting the Puerto Rican community, and to determine the effect of these stressors on biological response and disease specific outcomes. In this population, we will evaluate physiologic measures of stress related variables, measures of factors related to acculturation and migration, social support, vitamin intake and blood concentrations, assess physiological response through measures of allostatic load, and assess measures of cognitive and physical function.

We will test the overall hypothesis that: **Within the Puerto Rican older adult population in Massachusetts, greater levels of stress, associated with poverty, migration, acculturation and perceived discrimination, leads to greater allostatic load, and subsequently to adverse health outcomes, including depression and physical and cognitive impairment. We further hypothesize that limitations in social support and low vitamin intake and status accelerate this progression from stress to disability; that these associations are modified by genetic variability; that markers of inflammation can contribute to understanding these mechanisms; and that interventions can be developed to alleviate this progression.**

A center grant is well suited for this research question, as it provides the forum to include a collaboration of experts in the areas of the basic and behavior sciences, epidemiologic research, and

neuropsychology. In addition to this research team of scientific experts, this Center is well-positioned to test intervention programs through a team of field specialists currently working with the Hispanic community. Our collaborating community center, whose primary clientele is Puerto Rican, is established to enhance the well being of minorities in the greater Boston area, by offering a variety of services that range from social intervention to health and nutrition and to legal services.

The Center plan includes an integrated set of 4 research projects and 3 support cores. Project 1 will be a cohort study to examine this set of associations both cross-sectionally and with a 2 y follow-up for evidence of decline. The other 3 projects will build from this cohort, so that information can be shared across a spectrum from community and sociologic understanding to biological mechanism. As such, the full set of projects is summarized as follows:

Project 1: Prospective (2 y) cohort study of Puerto Rican older adults. We will investigate both baseline and 2 year prospective associations between psychosocial stressors and allostatic load; and in turn, allostatic load and functional decline, specifically depression, cognitive decline and physical disability; along with the role of social support, and vitamin intake and status in modifying these associations.

Project 2: Sociological investigation of psychosocial stressors and their measurement. Using both qualitative and quantitative methodology, we will gain contextual understanding of the sources of stress in this population that relate to allostatic load, and will adapt instruments for its measurement.

Project 3: Intervention studies. Using subsets of the baseline study, we will investigate the effectiveness of three different 2 y interventions in reducing indicators of allostatic load. Each is designed to be feasible for expansion by community agencies if effective. These include: 1) vitamin supplementation; 2) food coupons and nutrition education; and 3) social support and participation.

Project 4: Investigation of genetic contributions to allostatic load. We will explore the relationship between selected gene variants and allostatic load, at baseline and with change over time; and will investigate the interaction between gene variants and responses to the differing nutrition and social interventions.

In order to efficiently serve these 4 integrated research projects, we will coordinate data collection and processing through 3 Core facilities:

Core A: The Administrative Core will serve as the main coordinating center for budget related issues, report preparation, field operations, intercommunication between projects and investigators, organization of meetings, and will oversee the pilot projects program.

Core B: The Statistics Core: This core will receive all data, assure its quality control and confidentiality and assist with statistical design and analysis.

Core C: The Laboratory Core will be responsible for the processing of laboratory samples (blood and urine) for all projects.

Interdisciplinary Strategy:

The great advantage of this Center is the ability for Scientists across a broad range of disciplines to communicate toward understanding a common problem. We know that older Puerto Ricans have excess risk for a number of health problems, we also know that they are more likely to live in poverty, to have lower education, and to have relatively poorer nutritional status than the general population. Because most immigrated during their lifetime from the island of Puerto Rico and do not speak English, they live with sources of stress that may differ from those of other risk groups. In order to understand how their environment and life situation may translate into greater health risk involves an understanding of the sociology, psychology and biology. We have therefore assembled a group of scientists from the fields of sociology, psychology, human behavior, biology, nutrition and genetics to work together to gain a broader understanding of the spectrum of events that contribute to health disparities in this population so that we may better understand how to effectively improve the situation. We intend to meet as a group regularly to learn from each other and to contribute to each other's work.

B. Setting and Facilities:

The primary activities of this Center will be based at the USDA Human Nutrition Research Center on Aging (HNRCA) at Tufts University, along with collaborations with the Department of Psychiatry at the New England Medical Center (NEMC), the Department of Sociology and Anthropology at Northeastern University, and La Alianza Hispana, a community agency dedicated to serving the Latino community in the Greater Boston area. Together, these four institutions provide the facilities to examine the issue of stress, nutrition and health in the Puerto Rican Community from the psychosocial situation in the community to the cellular level. These sites are well positioned to carry out this research, each contributing the expertise and institutional facilities required.

The mission of the HNRCA is to determine the role of nutrition in health and aging and the effects on the most vulnerable populations are of considerable interest and importance to that mission. The laboratories of the HNRCA, as described in the resources section, have state of the art equipment and methodologies and are well equipped to make all the biologic measures required to assess nutritional status and allostatic load. The Dietary Assessment and Epidemiology Research Program, as the lead program for this Center has extensive expertise in field and epidemiologic research with low income populations, including most relevantly, an earlier cross-sectional representative survey of more than 1000 elders to study the health and nutritional status of elderly Latinos in the state of Massachusetts. Dr. Tucker directed that study and Dr. Bermudez served as field director and co-investigator. They are, thus, fully experienced in the questionnaires and field assessments to be used in the cohort study. Dr. Bermudez also has extensive community experience with nutrition interventions and is well qualified to lead the intervention piece of this Center. As leader of the recently upgraded genetics laboratory, Dr. Ordovas has state of the art equipment and extensive experience with determination of genetic variants and in the analysis of their interaction with environmental exposures to impact on health, and has particularly worked in areas relevant to allostatic load, focusing on gene effects on fat and carbohydrate metabolism. Dr. Martin focuses his research on the effects of antioxidants on inflammation and his project will contribute a better understanding of the role of nutrients and inflammation to the allostatic load and functional decline in this population.

In our work on vitamins and cognitive function, both Drs. Tucker and Martin have been working with Drs. Marshal Folstein and Dr. Scott at the Department of Psychiatry at NEMC. Dr. Folstein is a neuropsychiatrist and Dr. Scott is a clinical and research neuropsychologist, and they will contribute to the projects through their input on cognitive assessment in the community. Our statistics core will be directed from NEMC in their Center for Biostatistics directed by Dr. John Griffith. We are currently working with Dr. Griffith, and his well-staffed and organized center for an NIA funded project on Nutrition and Cognition (PI Dr. Folstein). The Department of Sociology and Anthropology at Northeastern, chaired by Dr. Falcon, will provide a social science context to the project, providing a better understanding of the lives of these generally low income urban Puerto Rican elders and a better understanding of culturally relevant methodologies for assessing their exposure to stress and to their means of social support. This work will lend support to both the cohort study and to the interventions.

Finally, our partners in the community, La Alianza Hispana, will be of central importance in our communication with the community and in gaining an understanding of their concerns. As the oldest and largest Hispanic serving institution in the state, they are well-connected with numerous agencies and health organizations that serve Puerto Ricans. This community based, non-profit organization is dedicated to promoting Latino self-determination, advocating for equal access to basic services, and combating the effects of poverty and discrimination. They administer a variety of programs from elder day care and literacy to job placement and legal assistance. We have worked with them for many years and they have been instrumental in the development of this application. They will work closely with each of the projects working in the field (1-3) and will be centrally involved in communication with the community. We will use their facilities and work with their staff in implementing the proposed interventions.

Institutional Commitment

All of the collaborating institutions, including the HNRCA at Tufts University, the department of Psychiatry and Center for Biostatistics New England Medical Center (NEMC), the Department of Sociology and Anthropology at Northeastern University, and La Alianza Hispana, are committed to the success of the proposed Center. Letters to this effect are included from Dr. Robert Russell, Director of the HNRCA, Dr. Jeffrey Blumberg, Associate Director of the HNRCA, Dr. Irwin Rosenberg, Director of the Neuroscience laboratory at the HNRCA and Dean of the School of Nutrition Science and Policy at Tufts University, Dr. Marshal Folstein, Director of the Department of Psychiatry at NEMC, Dr. Luis Falcon, co-investigator and Chair of the Department of Sociology and Anthropology at Northeastern University, and Mr.William Rodriguez, Director of La Alianza Hispana. The goals of the Center are consistent with each of the missions of the collaborating institutions and each has demonstrated a strong commitment to investigation and intervention in the area of health disparities. As such, the necessary space and needed cooperation within each institution is assured.

C. Proposed Use of Human Volunteers:

In order to study the effects of stress on physiologic measures of allostatic load and, in turn, on physical and functional outcomes, we will organize the Center activities around a central prospective cohort study of, at baseline 1625 Puerto Rican adults, aged 60-75 years. Of these participants, 375 will be randomized into one of three 24-month interventions (125 each to either vitamins, food and nutrition program, or social support and stress-reduction) (Project 3). Several subjects will also be selected from differing socio-economic strata for more in-depth ethnographic interviews to gain a better understanding of the social context (Project 2). Plasma will be drawn from all subjects for measurement of allostatic load and nutritional status (Project 1) and DNA (Project 4). A subset of 500 subjects (375 intervention and 125 randomly selected from the remaining cohort) will also have more extensive measurement of blood samples for markers of inflammation (Project 5. With an anticipated loss to follow-up of 20%, we expect to have at least 1000 non-intervened cohort subjects and 100 in each of the three intervention groups available to assess change in allostatic load and health measures over the 2 year follow-up period.

D. CPHHD Organization and Administration:

The Director for the proposed Center, Katherine L. Tucker, is a specialist in Nutritional Epidemiology. Dr. Tucker was previously the PI of a study of nutrition and health among a representative sample of Hispanic elders living in Massachusetts and a comparison group of non-Hispanic white elders living in the same neighborhoods. This focus of this Center grant--stress in the Hispanic community, and the effects on diet and disease specific outcomes--is a natural outgrowth of that work, which demonstrated significant health excess among the local Puerto Rican population. Dr. Tucker has worked with almost all of the key personnel on this Center project. Dr. Bermudez and Dr. Falcon were co-investigators of our earlier Hispanic elders study. Dr. Martin later joined in some of the analysis, including the assessment of vitamin E for that group. As noted above, Dr. Tucker is currently the Principal Investigator for the Tufts subcontract of a large study of vitamins, homocysteine and cognitive function in homebound elders, headed by Dr. Marshal Folstein. She is also a co-investigator on Dr. Ordovas' study of genetic polymorphisms and lipid metabolism and has collaborated with him on publications on diet-gene interactions(Corella, Tucker et al. 2001; Ordovas, Corella et al. 2002).

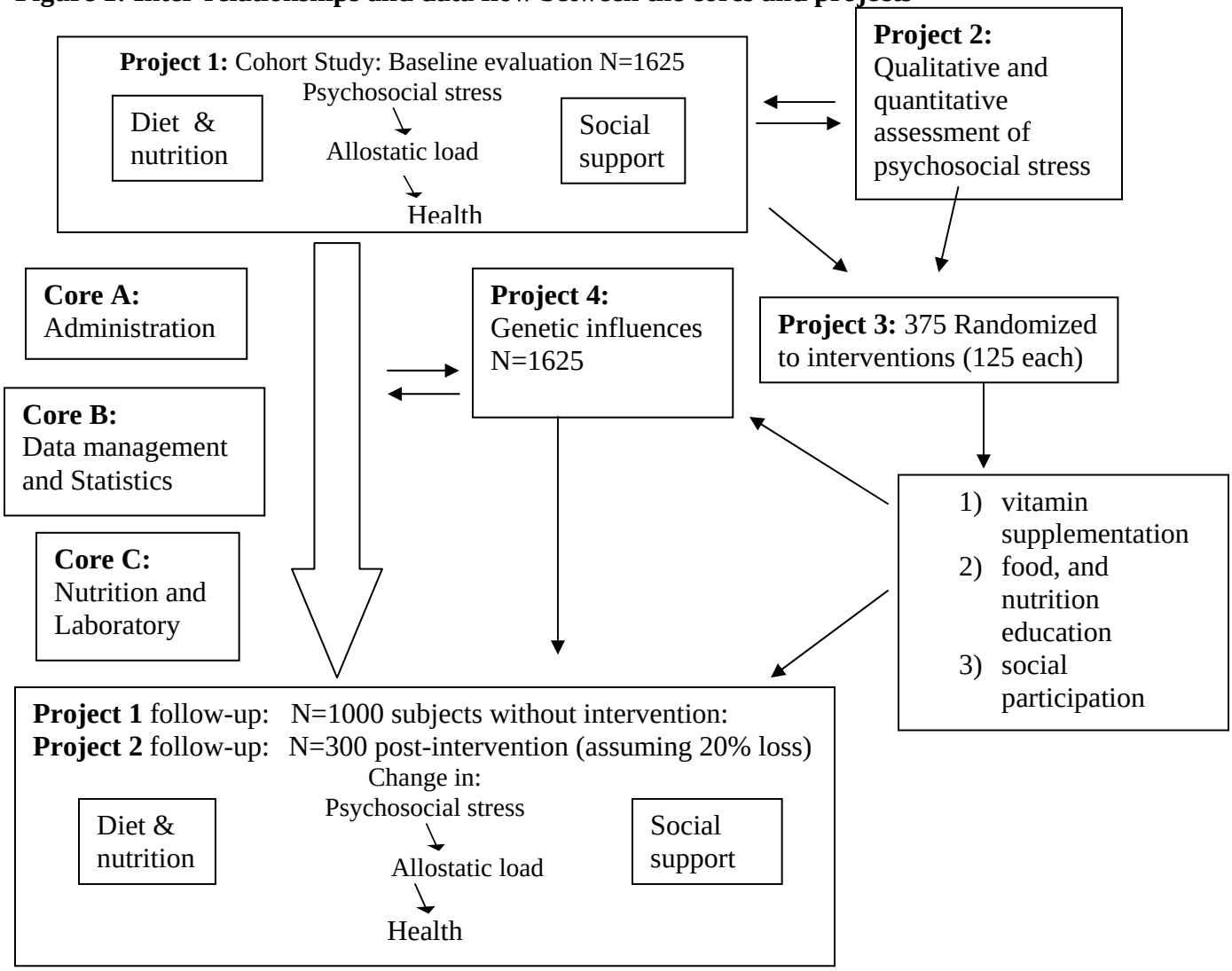
The key personnel for this proposed Center have been meeting routinely to discuss the design of this project and the preparation of this proposal. The coherence of this group is ensured by a strong administrative core, through which we will continue to arrange for regular meetings and regular communication among investigators. The central data management and statistics core will ensure linkage of data in an organized way that will make it accessible to all investigators. The laboratory core will ensure that the processing of all plasma and urine samples proceed efficiently, separated and prepared for the respective laboratories as outlined in the projects and that the data are sent to the statistics core for integration into the main data set.

Detailed Description Of The Interdisciplinary Collaboration

Project Synergy

This cohesive set of five projects offers a unique opportunity to combine a diverse set of expertise from sociology and epidemiology to genetics and biochemical mechanism. Their inter-relationship is presented in Figure 1. The Epidemiological cohort (Project 1) will provide baseline data, examine relationships between psychosocial burden in the Puerto Rican population, the physiological burden imposed by these stressors and level of functional status, as assessed by depression, cognitive function and physical function as well as changes in these measures over a two year time period. Building from this project we will, importantly, build a better understanding of the social context of life for older Puerto Ricans living in Boston, by including qualitative interviews with a random sample of participants (Project 2). These in-depth discussions will assist us in interpreting the quantitative data we gather on psychosocial stress and social support. Instruments on these social factors exist for the Mexican American population, but only limited adaptation for Puerto Ricans has been done. At the baseline interview, we will include several scales and question sets. From both our contextual understanding through ethnography and with scaling techniques, we will examine the validity and reliability of the question sets for this population. We expect this to result in reduced scales that more efficiently capture the reality for this group.

Figure 1: Inter-relationships and data flow between the cores and projects



In addition to a proposed pathway from stress to allostatic load to disability, we propose in Project 1, that this pathway may be modified by nutrition and/or social support. This will be examined prospectively in the cohort. In addition, we will examine 3 subsets of participants in intervention projects (Project 3). In the first, we will test the hypothesis that vitamins can alleviate these outcomes by providing vitamin supplements; in the second, we test the importance of broader aspects of food and nutrition with an educational program that supports dietary change through incentive coupons to purchase fruit and vegetables; in the third intervention, based largely on the experience of our collaborators at La Alianza Hispana, we will test the hypothesis that social support and connectedness, along with access to services and information, but without a specific focus on nutrition, may on its own have beneficial modifying effects.

While we expect that the hypotheses explored in the above projects will be confirmed with the general group, we are also aware that genetic variation affects how the body responds to environmental stimuli. Although we are rapidly gaining an understanding of the importance of genetic variants to health outcomes, we still have little information on the prevalence of these variants in susceptible subgroups or of their importance in the Puerto Rican population. We will, therefore, estimate the frequency of multiple genetic variants at candidate loci selected for functions relevant to this application including: syndrome X, hormone status, inflammation, stress, behavior and cognitive function (Project 4). Key genetic variants will then be tested in interaction with diet and stress measures in relation to response over the 2 year follow-up for the intervention groups and the larger cohort control.

A central response to stress that is not strongly featured in the currently used measure of allostatic load is inflammation(DeGraba 1997; Ridker, Cushman et al. 1997; DeGraba 1998; Barone and Feuerstein 1999). Inflammation has recently been the subject of intense research and has been shown to be predictive of stroke and heart disease(Ridker, Cushman et al. 1997). We believe that inflammation is of great importance in the cascade of events from environmental and psychosocial stress to disability and therefore propose to analyze our data with both the existing allostatic load measure plus with an additional measure of C-reactive protein (Project 1). In our previous representative survey, we documented the significantly greater prevalence of diabetes, depression, cognitive limitation, physical disability, and poor nutritional status even in relation to a relatively low-income comparison group of non-Hispanic white elders living in the same neighborhoods(Falcon and Tucker 2000; Tucker, Bermudez et al. 2000; Tucker, Falcon et al. 2000; Bermudez and Tucker 2001; Tucker KL 2001; Chen H 2002; Castaneda, Bermudez et al. in press; Lin H In press). With the assistance of this Center, we will be able to look more closely within this high-risk population to gain a better understanding of the mechanisms and pathways associated with these health disparities. This set of projects offers a unique and exciting opportunity for diverse group of investigators to learn from each other in examining the range of sociological, psychological and biological events that contribute to the greater prevalence of health conditions and functional disability in the Puerto Rican population.

Three cores, (administrative, statistics, and laboratory) will provide support to the 4 projects. The combined use of these cores and indeed, overlapping use of the same data they produce, will provide tremendous efficiency over what would be required for individual projects. The continued interface for communication through the administrative core will be of central importance to the cohesiveness of the study and to maximal efficiency and utility of the data produced by scheduling regular meetings and setting up email communication systems between partners. This core will also ensure compliance with budgetary and reporting requirements and will serve as the main point of communication with the Human Investigation Review Boards to ensure total ethical compliance.

The statistics core will ensure that data is properly and carefully handled from all projects and that final cleaned data are available to investigators as needed. This central data management function is essential to ensure that all investigators use the same cleaned and verified data that is not confused with older versions or combinations. This will ensure that data errors will be minimized and will improve efficiency by avoiding

redundant variable formation and cleaning. In addition the role of this highly experienced center in advising and assisting with statistical design and analysis will be critical in the production of quality analyses across projects.

The laboratory core will assure that samples are handled, stored and analyzed properly. Our laboratories at the Human Nutrition Research Center operate under the highest standards with systems in place for tracking and quality control for all assays proposed. In addition to continual calibration with standards, it is standard practice for the laboratories to rerun samples that appear out of range on the first analysis. Under the guidance of Dr. Martin and Ms. Perrone, samples will be separated into appropriate storage tubes and sent to the appropriate laboratories for processing at the appropriate times. The data will then be organized under the Nutrition Evaluation Laboratory's data management system in spreadsheet format and sent by FTP to the data center as batches are completed and checked. This central coordination of samples will ensure that they are used efficiently and effectively for the analyses required.

Strategies to Foster Intra- and Inter-Center Collaborations

These projects were designed to be inter-active and they are highly dependent on each other for use of data and expertise. To differing degrees, all investigators will contribute to Project 1, through their input on the development and testing of specific indicators on the questionnaire (For example Dr. Falcon for indicators of psychosocial stress, social support, migration history and acculturation; and Drs. Scott and Folstein for cognitive assessment); and for expertise on biologic markers (For example, Drs Blumberg and Martin for antioxidants, Dr. Rosenberg for B vitamins and Dr. Ordovas for genetic markers). The focus groups (Dr. Bermudez) and ethnography (Dr. Falcon) will inform all of the community-based work. The community indicators will be associated in most projects with the biologic outcome measures. Thus, by design, it will be critical for the investigators to meet regularly and to exchange information. This is one exciting aspect of the Center, as each of the investigators will gain a broader outlook by understanding the rationale and methodology for approaches in complementary areas. To this purpose, we will institute weekly meetings of all key personnel. In planning this application, we have already been meeting and find that it is a very effective way to share information and ideas.

In addition, we will have, as described more fully in Core A, both a steering committee and external advisory committee. Our internal advisory committee will include Dr. Folstein, Dr. Blumberg and Dr. Rosenberg from the NEMC and HNRCA. These senior investigators with expertise in aging, cognitive decline, antioxidants and B vitamins, will meet with the PIs and Core leaders will meet with the steering committee on a quarterly basis to contribute their suggestions and ideas toward the effective implementation of the Center. An external advisory committee consisting of both Scientists and Community Leaders (To be named) will meet annually with the steering committee after being provided with a summary of progress for the Center.

In order to engage and reach a larger group of investigators who are interested in health disparities and may be interested in our project, we intend to develop a website and to publicize its address so that activities of the center will be widely available. The website will include the ability to subscribe to an email list serve, which we will use to contact interested members when we have new activities or research findings, and to publicize our pilot research project opportunities. We will also hold periodic seminars on our research and will invite those on this list serve as well as colleagues in our respective institutions. Through our pilot projects program (years 2-4) we expect to engage additional collaborators in the center, and will encourage applications for multidisciplinary projects from both the social and more basic sciences. More detail on the pilot project program is provided at the end of this application.

We are pleased to hear that the NIH considers meetings across PIs involved in these Center grants to be of central importance. In our earlier funded project on Hispanic elders, Dr. Tucker participated in meetings with PIs of similarly funded projects. These were extremely motivating and informative and led to frequent contact between projects, including joint planning of sessions at the annual Gerontology meetings, as well as collaborative work on a book, entitled "Minorities, Aging and Health" for which Dr. Tucker contributed a

chapter on "Nutrition among Hispanic Elders in the US"(Markides and Miranda 1997). We expect that the group of projects funded here will be equally interactive and that the whole of the projects will contribute to more than the sum of its parts.

We have included one trip per year for this purpose in each of our project budgets. In addition, we intend to use external vehicles, such as our HNRCA seminar series, to invite investigators from other projects to present their work here at one of our sites, and to take that opportunity to discuss possible comparative or collaborative work, as appropriate.

Significance of the Puerto Rican Center on Health Disparities

The ability to integrate projects across a broad range of disciplines through the mechanism of a Center grant offers tremendous advantage to studying the complex set of events linking environmental and social stressors to functional health outcomes, via numerous biological mechanisms. This set of projects will be able to investigate the role of stress and allostatic load in the Puerto Rican population, a group demonstrated to have significantly greater prevalence of several health problems, including diabetes, depression and physical disability. In the process, investigators from a range of disciplines will broaden their perspective on these issues. We expect that results from this integrated set of research projects will provide a better understanding of factors contributing to health disparities—and in ways to intervene to reduce the disparities--both in ways that are specific to this particular high-risk group, and in aspects that are generalizable to other populations.

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